

ADVERSE REACTIONS FOLLOWING VACCINATION



NATIONAL IMMUNISATION MISSION

Ministry of Health & Family Welfare
Government of India

1989

COMMUNITY HEALTH CELL

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FOREWORD

The National Technology Mission on Immunization has been taken up to control the vaccine preventable diseases, which today account for a heavy disease burden in children. The Mission reflects the urgency and commitment to achieve universal immunization coverage as early as possible and to sustain that level.

High quality of services is essential to meet the objective of disease control. Additional inputs have been provided to make field operations feasible. Training programmes for all personnel have been given high priority to ensure quality services. Immunization is cost-effective and safe.

The reactions that follow vaccination are generally mild and of a short duration. Serious reactions are also known to occur but these are extremely rare and form a small fraction of similar type of complications that occur as a result of the disease itself. Neurological syndromes can also occur spontaneously in infants and vaccination may only be coincidentally related.

We have, however, been concerned about some incidents of severe reactions and deaths which resulted due to improper handling and administration of the vaccines. Such incidents were avoidable and indicate the need for strict vigilance and regular field monitoring.

This document summarizes information on severe reactions and deaths following vaccination. The purpose is to provide information on severe reactions so that complications due to faulty implementation could be prevented and if these occur, children are promptly diagnosed and adequately treated. The state governments have constituted expert committees to ensure prompt and thorough investigation of any severe reaction reported.

I acknowledge the cooperation of the state health authorities in sharing the investigation reports, based on which, this document has been prepared.

New Delhi
13 February, 1989

S.P. SHUKLA
Special Secretary
to the Government of India
Ministry of Health & Family Welfare

ADVERSE REACTIONS FOLLOWING VACCINATION

1. INTRODUCTION

1.1 Reactions Inherent to vaccination

The reactions that commonly follow vaccination are mild fever, redness, tenderness and pain at the site of injection. Fever and rash on the 6th or 7th day after measles vaccination has also been reported. Despite the safety of vaccines serious complications can also occur. Although their rates are difficult to estimate precisely, it is known that they are a mere fraction compared to the complication ratio arising out of the diseases themselves. The estimated rates are shown below:

Table-1
Estimated Rates of Adverse Reactions

Vaccine	Adverse reactions	Complication Rate / 100,000	
		Disease (Cases)	Vaccine (Immunizations)
1	2	3	4
DPT	Permanent brain damage	600-2000	0.2 - 0.6
	Death	100-4000	0.2
	Encephalopathy / encephalitis (including seizures focal neurological signs, coma, Reye's syndrome)	90-4000	0.1 - 3.0
	Convulsions	600-8000	0.3 - 90
	Shock	--	0.5 - 30
	Encephalitis / encephalopathy	50-400	0.1
Measles	Subacute sclerosing panencephalitis	0.5-2.0	0.05 - 0.1
	Pneumonia	3800-7300	--
	Convulsions	500-1000	0.02 - 190
	Death	10-10000	0.02 - 0.3
	Disseminated BCG infection	--	0.1
BCG	Osteitis / osteomyelitis	--	0.1 - 30
	Suppurative adenitis (children under 2 years)		100-4300

(Source: WHO Chronicle 1984, 38,3:95--98).

Paralytic poliomyelitis is the only serious adverse reaction associated with OPV. The risk is increased in immuno-deficient children. In a 10-year WHO collaborative study, the risk of vaccine associated paralysis was estimated to be about 1 case per million vaccinees and the risk of a close contact of a vaccinee developing paralytic polio was 1 case per approximately 5 million doses distributed.

1.2. Complications due to faulty techniques

Complications due to faulty techniques are avoidable if guidelines for administering the vaccine are followed. In this country, the complications arising out of faulty techniques are the main problems as opposed to the inherent risks.

1.2.1. Abscesses

The most common complication is the formation of abscesses following the use of inadequately sterilized syringes and needles. Abscesses require prompt attention from the medical officers. In rare instances, in the absence of adequate medical care such abscesses can lead to death.

1.2.2. Post-measles vaccination complications

Fever, profuse watery diarrhoea and vomiting within a few hours of measles vaccine administration have been reported. The case fatality rate in these incidents was high with death occurring within 24 to 48 hours after the onset of symptoms. Although the precise cause of the symptoms and deaths has not been identified the most likely reason appears to be contamination of the vial of measles vaccine. The symptoms of watery diarrhoea, vomiting and fever within a few hours of vaccination and death in 24 to 48 hours after the onset of symptoms reported in these incidents are suggestive of toxic shock syndrome. In the incidents investigated the quality of the services was poor with high probability of contamination of the vaccine vials.

1.3. Temporal association

The vaccines are usually administered to children at an age when infections are common. Some of the reactions reported may have only a temporal relationship to vaccination, the primary cause being unrelated to vaccine administration. Investigations are necessary to establish the causal relationship. It is important that children of the same age group in the area who did not receive vaccines are also examined.

Some conditions, particularly fever and neurological syndromes, also occur spontaneously among unimmunized children. Against this background of disease, it is sometimes difficult to determine if a recent immunization is causally or merely coincidentally related to illness. Convulsions for example, may follow DPT or measles immunization, but the background rate is high. At ages 3-15 months, the monthly incidence rate of convulsions ranges from 0.8 to 1.4 / 1000 children (WHO Chronicle 1984, 38, 3:95-98).

2. TOXIC SHOCK SYNDROME

Toxic shock syndrome typically begins with high fever, vomiting, and profuse watery diarrhea, sometimes accompanied by sore throat, headache, and myalgias. The disease progresses to hypotensive shock within 48 hours, and the patient develops a diffuse, macular, erythematous rash with non-purulent conjunctivitis. Patients may be disoriented and cardiac and multi-organ dysfunctions may also be seen. Symptoms often include alterations in the level of consciousness, oliguria and hypotension which in severe cases may progress to shock and disseminated intravascular coagulation. Recovery occurs within 7-10 days and is associated with desquamation, particularly of palms and soles, hair and nail loss has also been reported following recovery. In the recovery phase, there is desquamation of at least the palms, soles, or digits and often of other skin areas as well.

Laboratory studies reveal elevated blood urea nitrogen, serum creatinine, bilirubin, and creatine phosphokinase levels, and white blood cell counts with marked left shifts. Platelet counts are low in the first week of illness but are usually high in the second week. A number of nonspecific laboratory abnormalities and present reflecting involvement of multiple organ systems including the hepatic, renal, muscular, gastrointestinal cardiopulmonary and central ner system. Cultures performed prior to administration of antibiotic usually yield *Staphylococcus aureus*.

Patients require large volumes of fluid to maintain perfusion and usually require intensive care. Parenteral administration of beta-lactamase resistant anti-staphylococcal antibiotic is recommended.

REFERENCES

1. Toxic shock syndrome. Textbook of Paediatrics - Nelson, pages 649-650.
2. CDC: Toxic shock syndrome United States 1970-1982. MMWR 1982, 31: 201-4.
3. Toxic shock syndrome. MMWR 1980, 29, 20: 229-230
4. MMWR 1980: 441
5. MMWR 1980, 30, 25
6. MMWR 1983, 32, 30: 399
7. Wannamaker L.W. Toxic shock: Problems in definition and diagnosis of a new syndrome. Ann. Intern. Med. 1982, 96: 775

3. REPORTED VACCINATION PERFORMANCE

The number of severe reactions and deaths following vaccination are rare as compared to the total number of children vaccinated. The year-wise number of children and pregnant women who completed the full course of the vaccines in 1985-86 to 1987-88 is shown in Table 2. The number of doses of DPT and OPV administered will be three to five times the number of children who received 3 doses of the vaccines.

Table-2
Reported Vaccination Performance

Year	Number vaccinated (in million)				
	MEA	DPT3	OPV3	BCG	TT2 / B
1985-86	0.32	15.18	9.89	12.39	10.29
1986-87	3.71	12.94	11.12	11.75	11.69
1987-88	9.99	16.52	14.37	16.22	14.61
1988-89* (April to Dec.)	7.94	11.81	10.95	11.92	10.22

* - Provisional.

4. SUMMARY OF REPORTED SEVERE REACTIONS AND DEATHS FOLLOWING VACCINATION - 1985 TO 1988

25 incidents of deaths have been reported since 1985. Three of the incidents were unrelated to immunization; 2 were due to the administration of drugs other than vaccines; 17 resulted following the administration of measles vaccine and 3 were associated with other vaccines (Table 3).

Table-3
Reported Incidents of Deaths Following Vaccination

Year	Incidents Total	Measles Vaccine	Other Vaccines	Other Drugs	Temporal
1985	1	0	0	1	0
1986	9	4	2	1	2
1987	4	4	0	0	0
1988	11	9	1	0	1
Total	25	17	3	2	3

204 children were reported to have received various vaccines (including 10 children who were given other drugs) in the 22 reported incidents. The 3 incidents which were unrelated to immunization have not been taken into account. 134 were reported to have had some reactions and 57 children died (Table 4).

Of the 17 incidents in which children died following the administration of measles vaccination, all but 13 children developed fever, vomiting and diarrhoea within a few hours of vaccination. 94 of the 135 vaccinated are reported to have had these symptoms and 42 children succumbed within 24 to 48 hours. 12 of the children had only abscesses. Some of the children received other vaccines along with measles vaccine. The provisional cause of death of one child who received measles vaccine 10 minutes prior to death was anaphylactic shock.

11 children out of 43 vaccinated with vaccines other than measles in 2 separate incidents in 1986 developed abscesses and 2 children died as a result. In one incident in 1988, 6 children out of the 16 children who received DPT vaccine developed fever, vomiting and diarrhoea and 3 children died within 24 hours.

Drugs other than vaccines were administered to 10 children in separate incidents in 1985 and 1986. Only one child could be saved.

Table-4
Number of Children Vaccinated

<i>Vaccine</i>	<i>Year</i>	<i>No. of Incidents</i>	<i>Vaccinated</i>	<i>With Reactions</i>	<i>Died</i>
<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>	<i>6</i>
Measles	1986	4	36	33	11
	1987	4	36	23	14
	1988	8	62	50	17
		1	1	1	1
Sub-total		17	135	107	43
Other	1986	2	43	11	2
Vaccines	1988	1	16	6	3
Other	1985	1	5	5	5
Drugs	1986	1	5	5	4
Total		22	204	134	57

5. MEASURES TO MINIMIZE RISKS

The following measures need to be ensured to minimize risks of adverse events following vaccination:

- Training programmes for all categories of personnel should receive the highest priority to ensure high quality of services.
- Vaccination sessions should be held on fixed days. The children should be collected at the subcentre or at a central point in the village. Door-to-door vaccination should not be conducted as such a strategy carries a high risk of break in the cold chain and contamination of the syringes and needles.
- Procedures for sterilization of syringes and needles should be scrupulously followed and monitored. Wherever feasible steam sterilization should be given preference over boiling.
- Use of a single sterile syringe and a single sterile needle for each injection.
- Issue of the vaccine to the field staff should be strictly monitored. Only required quantities of the vaccines should be taken from the PHC on the day of the session. Vaccines may be taken on the previous day only if these are carried in vaccine carrier with four fully frozen icepacks. Supervision should include measures to ensure that vaccine vials are not stored in the periphery and re-used subsequently. Batch number and expiry date of each vial should be recorded before issue.
- Measles vaccine should be reconstituted with the diluent provided with the vaccine. The diluent should be cooled before use. The vaccine should be kept on ice while in use. The children should be administered 0.5 ml of the vaccine in the arm subcutaneously. A separate sterile syringe and needle should be used for each injection.
- Vaccines should be discarded at the end of the session. *Opened vial of vaccine should not be reused under any circumstances.*
- Potentially harmful injectible drugs should be kept separate from vaccine vials and diluent.
- Field monitoring of the services must be regular so that any deficiencies could be noted and corrected in time. Reporting of abscesses by the health workers in their areas should be made compulsory.

The post of the District Immunization Officer was specially created to improve planning management and field supervision of the immunization programme. The DIOs should be responsible for ensuring regular and adequate field supervision and for maintaining quality of the services. Plans should be realistic. Critical analysis of the available resources should be made and the plans should take into consideration the logistics of vaccines and other supplies.

6. STATE INVESTIGATION COMMITTEES

The state health authorities have been advised to have a standing committee of an epidemiologist, a paediatrician and a microbiologist on call to ensure prompt and thorough investigation of severe adverse events. The names of the members of the State Committees is given at page 12

The Technical Committee should investigate any serious incident within 48 hours of its occurrence. The report of the Committee should be looked into by an independent referral group.

The Director of Health Services should issue a note giving the salient points or a letter which should be available to the press for publication. This popular version of the incident should be issued within 72 hours of the incident.

Copies of the full investigation report and comments of the referral group should be sent to the Ministry of Health and Family Welfare.

7. INVESTIGATION OF ADVERSE EVENTS

7.1 Field investigation and analysis of reports

The basic principles of field investigations of outbreaks can be adopted for the investigation of adverse events. The first principle is to examine the cases to confirm diagnosis. All children immunized during the particular session should be followed up and relevant details entered in the list given in Form I page 10. It is important that non-immunized children of the same age group in the locality are also examined to rule out temporal relationship. The details of the children vaccinated may be summarised as given in Table 5.

Table—5

Number of children vaccinated, with reactions and number of deaths

Date of vaccination:

Vaccine	Number vaccinated	No. with reaction	Date(s) of reaction	No. died	Date(s) of death

Operational aspects of the programme need to be carefully reviewed with special reference to procedures followed for collection, storage and issue of vaccines; methods adopted for the sterilization of syringes and needles (including the total quantities of syringes and needles available for a session) and frequency and quality of routine field monitoring of services.

Where the adverse events are unexpected and not easily explainable, it is important that the signs and symptoms of each case are carefully noted. The promptness and completeness of investigations is of prime importance.

Vaccine samples should be sent for testing to the National Control Laboratory. The samples should be well packed in ice and sent by a courier. The forwarding note should clearly state the circumstances under which the sample(s) is/are sent. It is important that the used vial with remaining vaccine is sent for testing along with unused vials of the same batch.

7.2 Write-up and report results

A report should be prepared detailing the investigations conducted. This report should start with general information regarding the place where the events occurred. The name of the state, district and PHC/ward should be clearly stated. The following points should be covered in such a report:

7.2.1. Cases :

- how and when the first symptoms were observed and who reported the event;
- who conducted the investigations and when were they started;
- how were the investigations conducted;
- number of children vaccinated and the type of reactions observed. The line list and summary tables should be attached with the report;
- whether any children of the same age group in the area, who were not vaccinated, had similar symptoms.

7.2.2. Clinical aspects:

- detailed clinical picture;
- treatment provided to the children;
- outcome of illness;
- Diagnosis by clinicians and observations, if any, made by them.

7.2.3 Operational aspects:

- how are immunization services generally provided in the area. Procedure followed on the day of the event;
- when and from where the vaccines were received. How were the vaccines stored and transported;
- how many syringes and needles were available and procedures followed for the sterilization of the equipment;
- who administered the vaccines and the training they received;
- have similar reactions been observed in the past and were not reported.

7.2.4 Laboratory investigations:

- samples sent for testing and the names of the laboratories. The testing of the vaccine can take two to four months depending on the vaccine and the tests Form II, page 11.

7.2.5 Suggestions and recommendations

- what was the likely cause of the adverse event;
- measures recommended to minimize the risks in future.

Date

(Name & Designation)

Reference:

Sokhey Jotna and R. Kim-Farley.
Investigation of outbreaks of vaccine preventable diseases, A field guide.
W.H.O. SEA/EPI/79.

LIST OF STATE COMMITTEES FOR THE INVESTIGATION OF ADVERSE EVENTS

STATE	NAME	DESIGNATION	
1. Andhra Pradesh (Regional Committees)		Prof. of Microbiology Prof. of Paediatrics Prof. of PSM	Osmania Med. College, Hyderabad
		Prof. of Microbiology Prof. of Paediatrics Prof. of PSM	Gandhi Med. College, Hyderabad
		Prof. of Microbiology Prof. of Paediatrics Prof. of PSM	Kakatiya Med. College, Warangal
		Prof. of Microbiology Prof. of Paediatrics Prof. of PSM	Siddhartha Med. College, Vijayawada
		Prof. of Microbiology Prof. of Paediatrics Prof. of PSM	S.V. Med. College, Tirupati
		Prof. of Microbiology Prof. of Paediatrics Prof. of PSM	Kurnool Med. College, Kurnool
		Prof. of Microbiology Prof. of Paediatrics Prof. of PSM	Guntur Med. College, Guntur
		Prof. of Microbiology Prof. of Paediatrics Prof. of PSM	Rangaraya Med. College, Kakinada
		Prof. of Microbiology Prof. of Paediatrics Prof. of PSM	Andhra Med. College, Vishakapatnam
3. Bihar	Prof. S.K. Sinha Prof. O.N. Jaiswal Prof. Surja Bhushan	Prof. of Microbiology Prof. of Paediatrics Prof. of PSM	Medical College, Patna
4. Gujarat	Dr. V.V. Kolali Dr. (Mrs.) S.N. Vani Dr. C.K. Purohit	Prof. of Microbiology Prof. of Paediatrics Prof. of PSM	
5. Haryana	Dr. M. Bhasin Dr. P.L. Jindal Dr. Ayyagiri	State EPI Officer Paediatrician Assoc. Prof. Microbiology	DHS, Haryana PMO, Bhiwani PGI, Chandigarh

STATE	NAME	DESIGNATION	
6. Himachal Pradesh	Dr. Lalita Behal Dr. Asha Goel Dr. D.P. Mohil Dr. N.K. Vaidya	Paediatrician Microbiologist State Imm. Officer Prof. of PSM	
8. Karnataka (State level)	Dr. T.M. Ramesh Dr. D.B. Meundi Dr. Meera Meundi Dr. K. Suresh	Addl. DHS Prof. Paediatrics Prof. Microbiology DDHS (MCH & UIP)	Dte. of Health Services MC, Bangalore MC, Bangalore Dte. of Health Services
Karnataka (Regional Bangalore)	Dr. Zaibunnasa Begum Dr. Shiwananda Dr. Janagurapadam Dr. Rajanna	Div. Jt. Director Assoc. Prof. Paediatrics Prof. of Microbiology Epidemiologist	Dte. HS, Bangalore MC, Bangalore MC, Bangalore MC, Bangalore
Karnataka (Regional Mysore)	Dr. G.C. Suvarna Dr. Ankegowda Dr. M.V. Kulkarni Dr. B.R. Lalithama Dr. Nagappa	Div. Jt. Director Prof. of Paediatrics Prof. of PSM Prof. of Microbiology Div. Dy. Director Div. Dy. Director	Dte. HS, Mysore MC, Mysore MC, Mysore MC, Mysore Dte. HS, Mandya Dte. HS, Mysore
Karnataka (Regional Belgaum)	Dr. Vishwanath Dr. P.V. Ashwath Dr. M.S. Sumithradevi Dr. S.S. Tallur Dr. Bangari	Div. Jt. Director Prof. of PSM Prof. of Paediatrics Prof. of Microbiology Div. Jt. Director's Office	Dte. HS, Belgaum KMC, Hubli KMC, Hubli KMC, Hubli Dte. HS, Belgaum
Karnataka (Regional Gulbarga)	Dr. C.R. Krishnamurthy Dr. C. Shivram Dr. C.S. Kamala Dr. V. Rajagopal Dr. S.N. Sarshetti	Div. Jt. Director Prof. of PSM Prof. of Paediatrics Prof. of Microbiology Div. Dy. Director	Dte. HS, Gulbarga MC, Bellary MC, Bellary MC, Bellary Dte. HS, Gulbarga
9. Kerala	Dr. N.S. Suguna Bai Dr. Muriel Sukumaran Dr. Abhayambika Dr. S. Bhaskaran	Prof. of Paediatrics Prof. Microbiology Prof. Medicine Dy. Dir. Health Ser. (MCH)	MC, Trivandrum MC, Trivandrum MC, Trivandrum DHS, Kerala
10. Madhya Pradesh (Regional Committees)	Dr. N.R. Bhandari Dr. B.S. Darbari Dr. S.N. Sharma Dr. Radhakrishnan Dr. S.D. Singh Dr. R.R. Bhagawat Dr. M. Ketkar Dr. K.C. Simlot Dr. C.L. Bicchu	Prof. Paediatrics Prof. Pathology Prof. PSM Jt. DHS, Bhopal Div. Prof. Paediatrics Prof. Pathology Prof. PSM Jt. DHS, Indore Div. Jt. DHS, Ujjain Div.	MC, Bhopal MC, Bhopal MC, Bhopal MC, Indore MC, Indore MC, Indore

STATE	NAME	DESIGNATION	
	Dr. R.K. Taliya	Reader Paediatrics	MC, Gwalior
	Dr. N. Tikka	Reader Pathology	MC, Gwalior
	Dr. A.K. Govila	Prof. PSM	MC, Gwalior
	Dr. S.N. Saxena	Jt. DHS, Gwalior Div.	
	Dr. G.K. Rahalkar	Jt. DHS, Sagar Div.	
	Dr. K.K. Kaul	Prof. Paediatrics	MC, Jabalpur
	Dr. M.A. Hafeez	Prof. Pathology	MC, Jabalpur
	Dr. Indra Datta	Prof. PSM	MC, Jabalpur
	Dr. S.S. Kawar	Jt. DHS, Jabalpur Div.	
	Dr. A.T. Dabke	Reader Paediatrics	MC, Raipur
	Dr. P.K. Pradhan	Prof. Pathology	MC, Raipur
	Dr. V.B. Saxena	Prof. PSM	MC, Raipur
	Dr. B.C. Pandey	Jt. DHS, Raipur Div.	
	Dr. K.N. Tiwari	Jt. DHS, Bilaspur Div.	
	Dr. R.C. Pandey	Jt. DHS, Bastar Div.	
12. Maharashtra	Committees constituted by region.		
14. Nagaland	Dr. K. Kathipu	Paediatrics	
	Dr. S.K. Kikon	ADH & FW, Epidemiologist	
16. Punjab	Dr. Manmohan Kaur	DDHS (MCH & EPI)	DHS, Punjab
	Dr. K.K. Gambhir	ADHS (TB)	DHS, Punjab
	Dr. Sudershan Khera	ADHS (MCH)	DHS, Punjab
	Dr. R.K. Sharma	State Epidemiologist	DHS, Punjab
	Dr. Surjit Kaur	OMO, BCG	DHS, Punjab
	DIO/DFPO/Paed/TB Off.	O/O Civil Surgeons	All districts
19. Tamil Nadu	Committees constituted by region.		
		Prof./Assoc.Prof. of PSM	4 Medical Colleges
		Prof. of Paediatrics	
		Prof. of Microbiology	
20. Tripura	Dr. S. Bhattacharjee	Jt. DHS (Epidemiologist)	DHS, Tripura
	Dr. Bikash Roy	Paediatrics	V.M. Hosp., Agartala
	Dr. N. Banerjee	Microbiologist	G.B. Hosp., Agartala
22. W.B.	PHOs & CMOs briefed		
	No committee		
25. Chandigarh	Dr. (Mrs.) K. Rawat	Paediatrician	SMO, Genl. Hosp., Chandigarh
	Dr. (Mrs.) Promod Gill	Pathology	SMO, Genl. Hosp., Chandigarh
	Shri H.C. Gera	Anti-Malaria Officer	DHS, Chandigarh
27. Delhi	Dr. (Mrs.) A. Vargeese	Prof. Microbiology	MAMC, Delhi
	Dr. P.C. Goyal	Paediatrician	Delhi Admn.
	Dr. P.K. Patnaik	Distt. Imm. Officer	Delhi Admn.

STATE	NAME	DESIGNATION	
30. Mizoram	Dr. Bixama	Paediatrician	Civil Hosp. Aizwal
	Dr. K.K. Ghose	Microbiologist	Civil Hosp. Lunglei
	Dr. Matawma	Epidemiologist	DHS, Mizoram.
A & N	Surg. Cdr. JS Nagra	Director Health Services	
	Dr. B. Shanmugam	Paediatrician	
	Major S. Gowale	Microbiologist	
Arunachal Pradesh	Dr. G. Yomcha	SFWO	
	Dr. M.K. Paul	Paediatrician	
	Dr. K.K. Pandey	Pathologist	

8. REPORT OF SEVERE REACTIONS AND DEATHS FOLLOWING MEASLES VACCINE ADMINISTRATION

8.1 Kheda, Gujarat, January 1986

Twelve children were given measles vaccine in village Baroda, Limbasi PHC, Taluka Matar in Kheda district on 27 January 1986. All 12 children developed reactions and one child died the next day. A total of 13 children were vaccinated on the day including one child who received only DPT and OPV. One of the 12 children was given DPT and OPV in addition to measles vaccine.

Diarrhoea and vomiting was a common complaint but some of the children had only diarrhoea or vomiting. All the children had fever. Four children were also reported to have convulsions. Symptoms developed within three to four hours of injection. All the surviving children developed abscesses.

A 30-month old female child, who died, had fever and profuse vomiting and diarrhoea. The child was taken to the PHC at 8.30 A.M. on 28.1.86. The child had low volume pulse and was cold and clammy to touch. The pupils were dilated and not reacting to light. The child was dehydrated and unconscious. Despite emergency resuscitating measures, the child died within 15 minutes of admission to the PHC. Post-mortem was not conducted.

Information of the severe reactions was received only when the child was admitted to the PHC. The medical officer and the staff of the PHC rushed to the village and examined all the children who were vaccinated the previous day. Six children were taken to the Civil Hospital, Kheda where three children were admitted to the hospital for three days. All the 11 children who received measles vaccine developed abscesses.

According to guidelines, vaccination sessions are held on fixed days by a team of a multipurpose worker and a health supervisor. The concerned ANM, absented herself from the immunization session on 15 December, 1985 and 13 January 1986. The scheduled session in Baroda village on 16 January, 1986 was cancelled due to a laparoscopic sterilization camp. The ANM vaccinated the children between 4 P.M. and 4.30 P.M. on 27.1.86 on a day when vaccination sessions were not scheduled. She left by the 4.45 bus for Kheda town as she was not residing at the subcentre.

The vaccine, according to the statement of the ANM was received by her on 23.12.85. The vaccine was reconstituted about a month prior to the vaccination of the children on 27.1.86. Syringes and needles were not sterilized before use.

The ANM was keeping vaccines in a refrigerator of a charitable hospital in Kheda town. One vial of measles vaccine was found in the refrigerator.

Post-mortem was not conducted. Vaccine vials were not sent for testing.

The report shows several serious lapses in implementation. The vaccines were issued several days in advance and there was no monitoring of utilization. The vaccines were kept in the periphery. The vial of measles vaccine was reconstituted one month prior to the administration of the vaccine. Syringes and needles were not sterilized 12 children were vaccinated from a 10-dose vial. Only 5 children were within 9 to 15 months of age. Session were not held on a scheduled day. The vaccinations were conducted late in the evening. The HW(F) did not reside in the subcentre.

List of Children Vaccinated on 27 January 1986

Sl. No.	Name	Sex	Age	Vaccine	Symptoms
1	2	3	4	5	6
1.	Ushaben M.K.	F	18 m	MEA	Fever, vomiting, diarrhoea
2.	Bhanubhai M.K.	M	12 m	MEA	Fever, diarrhoea, convulsions
3.	Rajniibhai T.K.	M	18 m	MEA	Fever, vomiting, diarrhoea
4.	Shilpaben A.D.	F	36 m	MEA	Fever, vomiting, diarrhoea
5.	Narmadaben M.P.*	F	30 m	MEA	Fever, vomiting, diarrhoea, convulsions
6.	Bhav nab en A.D.	F	10 m	MEA, DPT3, OPV3	Fever, vomiting, diarrhoea, convulsions
7.	Chandrakant D.R.	M	17 m	MEA	Fever, vomiting
8.	Gitaben D.R.	F	12 m	MEA	Fever, vomiting
9.	Bhanuben G.B.	F	12 m	MEA	Fever, diarrhoea, convulsions
10.	Manubhai G.H.	M	18 m	MEA	Fever, vomiting, diarrhoea
11.	Veenaben H.H.	F	12 m	MEA	Fever, vomiting
12.	Chandrakant D.N.	M	18 m	MEA	Fever, vomiting, diarrhoea
13.	Sonalben L.C.	F	8 m	DPT3 OPV3	None

Dist.

8.2 Kurukshetra District, Haryana, June 1986

The death of 2 children was reported in June 1986 following the administration of measles vaccine in village Dab Khora, Ladwa block, PHC Radurar. The incident was investigated by the Chief Medical Officer of the District.

A total of 16 children were vaccinated on 20th June, 1986 with various vaccines. 11 of these children received measles vaccine (The statement of the details of the children, however, showed 10 children who received measles vaccine). All the 11 children developed mild to severe symptoms of fever, vomiting and diarrhoea 4 to 6 hours following the administration of measles vaccine. In three children the symptoms were moderate and in three others these were severe. One child with severe symptoms died after 14 hours and the second child after 62 hours. One child was discharged from the hospital after complete recovery (Table 3).

One of the three children with severe symptoms was treated by a private practitioner and died in the village 14 hours after the administration of measles vaccine. The other child died in the early hours of 23.6.86 in the General Hospital, Kurukshetra. The third child who was first admitted to private hospital, then shifted to Civil Hospital, Ladwa and finally referred to the General Hospital, Kurukshetra, was discharged after full recovery.

The three children with moderate symptoms were treated at the Civil Hospital, Ladwa, and discharged after one day following full recovery. The type of treatment given in the hospitals was not mentioned in the report.

The vials of vaccines were reported to have been taken from the Civil Hospital, Ladwa and opened prior to the immunization session. Full vial of measles vaccine was consumed.

Syringes and needles were reported to have been boiled on kerosene stove in a sauce pan at the immunization site.

Semi-used vials of measles vaccine were not available for testing. Unopened vials of batch Nos. Z-903 and Z-906, tested at CRI, were found to be of standard quality.

Although the exact cause of severe reactions leading to deaths could not be pin-pointed from the investigations carried out, the possibility of improper storage of vaccine and use of improperly sterilised syringes and needles for vaccination could not be definitely ruled out. 11 children were reportedly vaccinated from a 10-dose vial. The records do not tally with the actual numbers vaccinated. 6 children were above 15 months of age at the time of vaccination, including the two children who died.

List of Children Vaccinated on 20th June, 1986

No.	Name	Sex	Age	Vaccine	Symptoms
1.	Niru Pal	M	2 m	BCG	None
2.	Baby	F	9 m	DPT, OPV	None
3.	Nasib Singh	M	10 m	DPT, OPV, MEA	Moderate
4.	Neena	F	10 m	DPT, OPV, MEA	Mild
5.	Jasbir Singh	M	6 m	DPT, OPV	None
6.	Karanjit Singh	M	18 m	DPT, OPV, MEA	Mild
7.	Jasvinder	M	8 m	DPT, OPV	None
8.	Charanjit Singh	M	2 m	BCG	None
9.	Tejinder Singh	M	9 m	DPT, OPV	None
10.	Sukhvinder Kaur	F	18 m	MEA	Moderate
11.	Prabheep Singh	M	18 m	MEA	Severe
12.	Beant Kaur	F	11 m	DPT, OPV, MEA	Moderate
13.	Malkeet Singh	M	9 m	MEA	Mild
14.	Geeta*	F	21 m	MEA	Severe
15.	Harpal Singh*	M	21 m	MEA	Severe
16.	Manjeet Kaur	F	21 m	MEA	Mild

* - Died.

8.3 Varanasi District, Uttar Pradesh, July 1986

Death of six children was reported from village Pachawam, Sewapuri PHC in Varanasi district on 9 July, 1986. The children had received measles vaccine on the previous day. In all, 10 children were vaccinated of whom 9 developed reactions.

Information regarding the severe reactions was received only when the two children were admitted in the hospital. Five children had died in the village by the time a team of doctors reached it on 9.7.86.

The incident was investigated by Dr. C.M. Chandra, Additional Director of Health Services; Dr. Mishra, state epidemiologist; Dr. Bhatnagar, Joint Director of Health Services and Dr. K.N. Agarwal, Professor of Paediatrics, Institute of Medical Sciences, Varanasi. Dr. Indra Bhargava, Deputy Commissioner (MCH), Ministry of Health and Family Welfare, visited the PHC on 11.7.88.

Of the 10 children vaccinated on 8.7.88, 9 had fever, vomiting and diarrhoea 4 to 6 hours following vaccination. 8 children were reported to have been given different vaccine combinations, 3 children received only measles vaccine, 2 were given DPT and OPV and 3 children received either DPT, OPV or DT. Only 2 children who were given measles vaccine were in the eligible age group. 3 pregnant women were also given TT vaccine on the same day. There was some confusion as to the total number vaccinated and the vaccines administered as the reports from different sources did not tally.

Five children died in the village or on the way to the hospital on 9 July 1986. One of the two children, admitted to the hospital in serious condition, recovered following treatment. According to the reports one of the 6 children who died had not received measles vaccine. 2 other children who received this vaccine did not have any reactions. One of the pregnant women vaccinated on 8.7.86 had a still-birth the next day.

The vaccines were administered by 2 female health workers and one male health worker.

The vaccines were received in the PHC on 5 July 1986 from the district headquarters. The vaccines were issued to the health workers in a vaccine carrier of 7.7.86. Ten children were reported to have been vaccinated on 7.7.86 without any reaction. Total number of vials issued to the health workers was not mentioned in the report. The ILR at the PHC was functioning at the time of the visit of the enquiry committee. The stock registers could not be checked as these and other records had been seized by the police.

Only 2 syringes were used by the health workers for the immunization of the children. The syringes and needles were not sterilized prior to use.

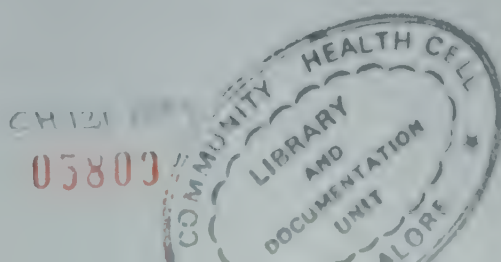
Two semi-used vials of measles vaccine along with an unused vial of the same batch number were found. One semi-used measles vaccine vial was found to be contaminated with *Staphylococcus intermedius* and the other with *Bacillus* species. The unused vial of the same batch No. M106N14B (Test report No. 10-4(1)/86-STs dated 2.12.86) was of standard quality. Unused vials of DPT, DT and TA vaccines of the same batch number were found to be of standard quality. Post mortem was not conducted.

The health workers were suspended by the state government.

List of Children Vaccinated on 8 July, 1986

Sl. No.	Name	Sex	Age	Vaccine	Severity
1.	Manish*	M	12 m	MEA, DPT, OPV	Severe
2.	Ramesh Kumar*	M	30 m	MEA, DPT, OPV	Severe
3.	Amit Kumar	M	12 m	MEA	None
4.	Pankaj Mishra*	M	36 m	MEA, DPT	Severe
5.	W. Dubey*	M	30 m	MEA, OPV	Severe
6.	Sandhya Singh*	F	24 m	DPT, OPV	Severe
7.	Anita Prasad*	F	36 m	MEA	Severe
8.	Ajay Kumar	M	36 m	MEA, DT	None
9.	Thanedar	M	30 m	MEA	Severe
10.	Purshuram	M	7 m	DPT, OPV	None

* - Died



8.4 Bhatinda, Punjab, July 1986

Three children were vaccinated with measles vaccine on 31 July 1986 in Heerke village, Sardulgarh PHC in Bhatinda district. Two of the children also received DPT and OPV. All the three children had severe diarrhoea and vomiting and were semi-conscious. Two children died.

One of the three children died at home without treatment. Another child was taken to a private practitioner in Ratia in Haryana and recovered. A 10-month old child was admitted to the Sardulgarh PHC. He was given Isolyte P. injection intravenously and micoren intramuscularly. Decadron was given by drip. Oxygen was also given to the child. The child died in the PHC.

The vaccines were administered by a medical officer of the rural dispensary, Makhewala, PHC Sardulgarh. The cold chain for vaccines was reported to be well maintained. Details were not provided in the report. The measles vaccine vial was said to be opened on the day of the session. There was no mention regarding the total number of syringes or the procedure followed for sterilization.

Semi used measles vaccine vial was found to be contaminated with Pseudomonas and Candida species. Unused vaccine vial of the same batch was found to be of standard quality. Post mortem was not conducted.

List of Children Vaccinated on 31 July, 1986

Sl. No.	Name	Sex	Age	Vaccine	Symptoms
1.	Rajvinder*	M	11 m	MEA	Fever, diarrhoea, vomiting
2.	Raj*	M	10 m	MEA, DPT, OPV	---
3.	Rinku	M	9 m	MEA, DPT, OPV	---

* -- Died

8.5 Rampur District, Uttar Pradesh, April, 1987

The death of three children was reported from Milak Bichaula village, subcentre Saanaiyasukh, Chamroha PHC, Rampur District in Moradabad Division on 8 April 1987.

The vaccines were administered on 7.4.87 and the children died in the early hours on 8.4.87. The report of the incident was received at the state headquarters in the afternoon of 8.4.87. The incident was investigated by Dr. Subodh Mittal, Addl. DHS, UP; Senior Paediatrician and the Divisional Addl. DHS on 9.4.87.

The vaccines were given by the HW(F) around 10.30 A.M. on 7.4.87. According to her statement one child each was given DT and TT vaccines and 3 children measles vaccine. She did not mention the administration of OPV. The villagers informed that only one syringe was used. According to them all the 5 children were also given OPV. The relevant records could not be checked as these had been seized by the police.

All the 5 children developed fever, profuse and frequent vomiting and diarrhoea. Three children were brought to the district hospital around midnight in serious condition. Two children died within two hours of admission. One of the children was semi-conscious, had convulsions and neck rigidity was noticed. The third child died around 8 A.M. on 8.4.87. Two other children, admitted in the morning of 8.4.87, have recovered following treatment.

The HW(F) joined only about 10 months prior to the incident. She did not reside at the subcentre but stayed in Rampur town. She had left the village before the adverse reactions developed.

All the children vaccinated were above the recommended age groups. The investigation report did not mention the date and quantities of the vaccines issued to the HW(F) and the conditions under which these were carried to the village. There was also no mention of the previous immunization sessions and whether there was any evidence of reuse of the vaccine vials.

Measles vaccine vials from the same batch taken from the district stores was sent to CRI, Kasauli for testing. The vaccine vial was found to be of standard quality. Used vials were not tested. *The post mortem of the 3 children did not reveal any significant findings.*

Details of children vaccinated on 7.4.87

Sl. No.	Name	Sex	Age (Years)	Vaccine	Symptoms
1.	Shabhu*	M	8	TT	Fever, vomiting, diarrhoea
2.	Mehtab*	F	3	MEA	Fever, vomiting, diarrhoea
3.	Mohammad*	M	4	MEA	Fever, vomiting, diarrhoea
4.	Mohammed	M	10	MEA	Fever, vomiting, diarrhoea
5.	Nabbu	M	6	DT	Fever, vomiting, diarrhoea

* - Died

86 Trichur District, Kerala, May 1987

The death of two children following the administration of measles vaccine was reported from Wadakkancherry in Trichur district on 28 May, 1987. The incident was investigated by Dr. Sarada, Deputy District Medical Officer of Health and Dr. Siddardhan, Medical Officer in-charge of PHC Erumapatty.

Five children, 9 to 18 months of age, received measles vaccine at Government Hospital, Wadakkancherry on 27 May 1987 around 11 A.M. The vaccine was administered by a junior public health nurse (Jr. PHN) from Erumapatty PHC.

All the 5 children developed fever, vomiting and diarrhoea within an hour of vaccination, in addition 2 also had convulsions. All the children were brought for treatment in serious condition by 8 to 10 P.M. on the same day. The condition of the children and treatment received prior to hospitalization is not mentioned in the report.

One child (11 months of age) was brought back to the hospital from the bus-stand and examined by a paediatrician. The child was given ORS. The child was later admitted to the hospital around 11 P.M. in an unconscious condition. The child had high fever and convulsions. The child was referred to the medical college hospital the next morning but died on the way. The child, during the period of hospitalization was given ampicillin, gentamycin, furazolidone suspension and 5% glucose drip.

Another child, 18 months of age, was brought to a private nursing home at Wadakkancherry at 10 P.M. The symptoms included high fever, convulsions and vomiting. The child was cyanosed and did not respond to pain stimuli. The child was diagnosed as having encephalitis and was given oxygen, antipyretics and cold sponges.

Two other children were admitted for fever, vomiting and diarrhoea at 8.15 P.M. on 27.5.87. They were given ampicillin, furazolidone and ORS. Their condition improved.

Two vials of measles vaccine (Batch No. AO-306, date of expiry 20.3.88) was reported to have been brought by the Jr. PHN to the hospital, Wadakkancherry from the PHC Erumapatty on 3.5.87. The vials were kept in the freezer compartment of the hospital refrigerator along with the diluent. The investigation report does not mention anything about the remaining vials of measles vaccine, procedures followed for sterilization and number of syringes and needles available with the Jr. PHN.

8.7 Hissar District, Haryana, June 1987

The death of 3 children was reported in Petwad village, subcentre Petwad, PHC Khandakhori in Hissar district in June 1987 following the administration of measles vaccine.

The incident was investigated by Dr. Inderjit, Jt. DHS, Haryana and Dr. Mohini Bhasin, State Immunization Officer. Investigations were also made by Dr. Rodrigues, Director Grade Specialist, National Institute of Virology, Pune and Dr. K.C. Tayal, Deputy Asstt. Commissioner, Ministry of Health & FW.

There are conflicting reports on the total number of children vaccinated on 22.6.87. According to the mothers of the children in the village, 32 children were vaccinated on the day. According to the concerned health worker 20 children received measles vaccine and one child each received DPT and TT vaccines. Two other reports mention the vaccination of 18 children with measles vaccine.

The vaccinations were apparently started around 10.30 A.M. on 22.6.87 by house to house visits. This was not a scheduled session and the villagers were not aware of it. Among the first houses visited was one with 3 children. An already reconstituted vaccine was given to the 3 children. It was reported that the 3 children fell unconscious within a few minutes of vaccination and the health worker was accordingly informed. The health worker was not alarmed at the condition of the children and continued to vaccinate others.

Seven children had fever, vomiting and diarrhoea and in 3 of these children rash was also noted. The symptoms started within 15 minutes of injection. Six children were admitted to a private hospital in Narnaund. Two children died on the same day. The Chief Medical Officer was informed of the incident only the next morning. The four children in the private hospital were shifted to the General Hospital at Hissar on 23.6.87. One child, 4 years of age, died in the hospital on 24.6.87 at 5.30 A.M. The attending physician noted the cause of death as gastroenteritis and peripheral circulatory failure. The surviving children developed abscesses at the site of injection. Distension of the abdomen was also noted.

It was reported that the health worker had two vials of measles vaccine and vaccinated 9 children from each vial. The reconstitution of the second vial was confirmed by the villagers.

One syringe (5 ml) and a few needles were used for immunization. Sterilization procedures and guidelines for the use of a single sterile syringe and needle for each injection was flouted.

The HW was issued 40 doses (4 vials) of measles vaccine on 9.6.87. He is reported to have kept these vials at room temperature till 22.6.87. PHC Chandakheri had received 1000 doses of measles vaccine (Rouvax, Institute Mérieux Batch No. A-1434) from the district headquarters on 3.6.87. The refrigerator of the PHC has been out of order since April 1987 and the vaccines were reported to have been kept in the personal refrigerator of the Medical Officer of the PHC.

List of Children Vaccinated

Sl. No.	Name	Sex	Age (Years)
1	2	3	4
1.	Sandeep Kumar	M	6
2.	Manju Bala	F	4
3.	Gauri Shanker	M	2
4.	Sohan Lal	M	3
5.	Ritu Rati	F	5
6.	Manish Kumar	M	6
7.	Mewa	F	4
8.	Sushma	F	7
9.	Suman	F	2
10.	Rakesh	M	4
11.	Mukesh	M	8
12.	Rinku	M	1-1/2
13.	Pawan Kumar	M	2
14.	Suman	F	4
15.	Suman	F	1-1/2
16.	Suman	F	5
17.	Baljeet	M	5
18.	Pardeep	M	2
19.	Billa	M	1
20.	Subhash	M	1
21.	Pankaj	M	2
22.	Sunita	F	4
23.	Manoj	F	4
24.	Neena	F	7
25.	Ghanshyam	M	6
26.	Shiv Kumar	M	2
27.	Ashok	M	5
28.	Vinod	M	7
29.	Meena	F	1-1/2
30.	Parveen	F	7 months
31.	Pinki	F	7
32.	Vinod	M	7

According to the list of children attached to the report, only 5 children were in the age group 9 to 15 months. Three children were under 9 months of age and the other children were all above 13 months of age. Since only two vials of

measles vaccine were reported to have been used obviously 32 children could not have been vaccinated. Apparently some of the children received vaccines other than measles although there is no mention regarding the other vaccines in the report. The HW reported giving one child each DPT and TT vaccines. The issue, storage and use of these vaccines is not available in the report.

There are several facts which point to poor quality of services in the area and lack of supervision. It is a matter of concern that such a situation was allowed despite the training of medical officers at the District and PHC levels and the health workers.

The empty measles vaccine vials tested at CRI, Kasauli were found to be contaminated with Staphylococcus aureus and Pseudomonas species.

The liver, spleen, kidney, section of the small intestines were examined in the Department of Pathology, Rohtak Medical College. The material was received on 25.6.87 and report sent on 11.7.87 (PATH.D/-2497) and 21.7.87 (PATH.D/-2562). The sections of the specimens of liver, spleen and kidney showed advanced autolytic changes as a result of which structural details were lost and pathological changes could not be identified. The tissues were unsatisfactory for opinion. The specimen were examined several days after the death of the child.

Patchy areas of mucosal ulceration were seen in the two sections of the small intestine. In the affected areas there was some increase in inflammatory infiltrate and evidence of vascular congestion of submucosal oedema. At places the lymphoid tissue was prominent. Lymph nodes isolated showed non-specific reactive lymphadenitis. The histological changes were those of a non-specific inflammation.

8.8 Cuddapah district, Andhra Pradesh, September 1987

The death of six children in the age group 9 to 24 months was reported from Burujupalle village, PHC Galiveedu.

There were conflicting versions about the vaccines administered. The parents of the deceased children said that their children received both DPT and measles vaccine whereas the other children received only DPT. This was confirmed by the parents of the surviving children who were reported to have received only one injection. The HA, however, denied this and said that all the children were given both the vaccines. The total number of children vaccinated is also not clear.

Six children developed fever, vomiting and diarrhoea following vaccination on 28.9.87. They died in the night of 28-29.9.87. The medical officer of the PHC visited the village on 30.9.87 and reported the incident to the District Health Officer only on 1.10.87.

The PHC had received stocks of DPT and measles vaccines from the district stores on 19.9.87. The vaccines were distributed among the health workers of the PHC the next day who in turn distributed the vaccines to the health workers of the subcentres. The total quantities of the vaccines issued or the condition of storage of the vaccines during the period 20.9.87 to 28.9.87 is not known. According to the statement of the health worker these were kept in the ILR of the PHC.

Other factors related to vaccine administration such as the number of syringes and needles with the HW(F), procedures for sterilization, total number of children vaccinated is not mentioned in the report.

It was, however, reported by the HA that measles vaccination was conducted in 2 villages on 26.9.87 and in 3 villages, including the one where reactions occurred, on 28.9.87.

One vial of used and one vial of unused Rouvax live attenuated measles vaccine batch no. BO306 manufactured at institute Merieux, France, Date of Expiry 20.3.88 were received from the Directorate of Health Services, A.P. at CRI, Kasauli on 13.10.87. The used vial of the vaccine was found contaminated with — haemolytic streptococci. The sample passed the test for freedom from toxicity in guinea pigs. The quantity was insufficient for a similar test in mice. Potency, identity and stability tests were also not performed due to insufficient quantity of the vaccine. The unused vial of the same batch was found to be sterile and free from abnormal toxicity in mice and guinea pigs. The sample contained $10^{3.56}$ virus particles per dose (CRI test report no. 10-4(i) 87-STS dated 17.11.87).

8.9 Vijaywada District, Andhra Pradesh, May 1988

13 children were vaccinated at anganwadi centre, Seetharampuram ICDS block, Municipal Corporation, Vijaywada by the HW(F) on 19 May 1988. 8 children received DPT and OPV, 3 children DPT, OPV and measles vaccines and 2 children only measles vaccine.

5 children had severe reactions following vaccination. These children had high fever, vomiting and diarrhoea. One child died. 4 children were admitted to the University General Hospital and recovered following treatment.

The vaccination session was started around 11 A.M. The 10 month old child who died, was noted to have fever, vomiting and diarrhoea by 3 P.M. She was given paracetamol and slept from 7 P.M. till midnight. At 12.30 A.M. the mother noted that the child had high fever. Within the next two hours the child was taken to a private practitioner and then to a paediatrician. The child was not given any treatment and died at 3 A.M. on 20.5.88, less than 24 hours after vaccination.

From the vaccine expenditure statement as booked by the HW(F) in her tour diary it was observed that she had been using left over vaccine of the previous day. The statement enclosed revealed that she had taken 50 doses (5 vials) of measles vaccine on 30.4.88. On 13.5.88 she had 6 doses of vaccine left which the HW(F) said she discarded and used a new vial on 19.5.88.

Sterilization of syringes and needles was unsatisfactory.

The vial was tested at CRI and found to be contaminated with an aerobic spore bearer organism.

The incident was investigated by Dr. B. Nandraj Singh, Additional Director of Medical and Health Services (FW & MCH) who reached the site by the evening of 20.5.88 and examined the hospitalized children.

List of Children Vaccinated

Sl. No.	Age (Months)	Vaccine	Symptoms
1. O. Shivaparvathi	6	DPT, OPV	None
2. U. Rajeswari	5	DPT, OPV	None
3. P. Uperas	6	DPT, OPV, MEA	Fever, vomiting, diarrhoea
4. A. Venkatarao	12	DPT, OPV, MEA	Fever, vomiting, diarrhoea
5. O. Durgarao	13	DPT, OPV, MEA	Fever, vomiting, diarrhoea
6. B. Ramu	5	DPT, OPV	None
7. Pydala Babu.	5	DPT, OPV	None
8. Seela Radhika	8	DPT, OPV	None
9. P. Venkateshwarao	8	DPT, OPV	None
10. S. Nazeemunnisa	4	DPT, OPV	None
11. Jammu Papæ	8	DPT, OPV	None
12. B. Ramanammu	9	MEA	Fever, vomiting, diarrhoea
13. K. Veeralaxmi*	10	MEA	Fever, vomiting, diarrhoea

*Died

8.10 Aizawl, Mizoram, June 1988

Severe reactions in two children following the administration of measles vaccine at Tuikal 'B' subcentre, Aizawl district on 1.6.88 was reported. One child recovered following treatment while the other died on the 5th day following vaccination. The incident was investigated by a paediatrician and an officer of the Directorate of Health Services, Mizoram on 8 June 1988.

Measles vaccine was given to two children on 1.6.88. Both the children had fever, vomiting, diarrhoea and abscess at the site of injection. The children were treated at the Civil Hospital, Aizawl.

The vaccine was administered by the health worker (F). She had indented the vial of measles vaccine on 13.5.88 and had provided a list of 10 children she planned to vaccinate. However, the vaccine was not given to any of these 10 children but to six others. The remaining vaccine in the opened vial was left in somebody's house. After an interval of nineteen days, this vaccine was administered to the 2 children on 1.6.88.

During investigations it was found that the HW(F) had again indented for one vial of measles vaccine on 3.6.88 giving a list of 8 children. The vaccine was given to 2 children, of whom only one was on the list. The remaining vaccine was confiscated by the investigation team. At this time 5 vials of DPT (50 doses), one opened vial each of OPV and TT were also found with the HW(F).

Adequate number of syringes and needles were available with HW(F). These were reported to be boiled for 5 to 10 minutes before use.

Used vials of the vaccines were not sent for testing.

Children vaccinated were Vanlalmawia s/o D Nghmingthanga M 13 months of age and David s/o Vanhmune M 10 months. Both the children were given 1 dose of measles.

The HW(F) was placed under suspension and departmental proceeding initiated.

8.11 Dholpur District, Rajasthan, June 1988

The death of 4 children was reported from village Hasai, PHC Bari, Dholpur district, Rajasthan within 24 hours of measles vaccination on 4 June 1988. The incident was investigated by the state investigation committee comprising of the Prof. of Paed., Prof. of PSM, Associate Prof. of Microbiology, Jaipur Medical College and the State Immunization Officer.

One vial of TT and four vials of measles vaccine were issued on 3.6.88. 15 children in Rajabpur village were reported to have been vaccinated using 2 vials of measles vaccine. The remaining two vials of measles vaccine were kept in the refrigerator of the landlord.

The next day on 4.6.88 sixteen children were reported to have been given measles vaccine and 1 pregnant woman was vaccinated with TT.

Investigations confirmed the vaccination of 12 of the 16 children. 4 children were falsely reported to have been vaccinated. The vaccinations were given by door to door strategy. Measles vaccine was administered in the gluteal region intramuscularly. The syringe and needle were boiled in the first house and two children were vaccinated in this house.

The four children who died had high fever, profuse vomiting and diarrhoea 15 minutes to 2 hours following vaccination. 3 children died in the village by the same evening. One child was brought to the PHC hospital who died there. A fifth child with similar symptoms was hospitalized and recovered. The treatment given to this child is not mentioned.

Except for the two children in the first household who had only fever, other children developed abscesses or induration at the site of injection.

Although there were cases of gastroenteritis and heat stroke in the village, no deaths had been reported.

Used vials were not available for testing. These had been discarded by the health worker. Autopsy was not done.

8.12 Bilaspur District, Madhya Pradesh, June 1988

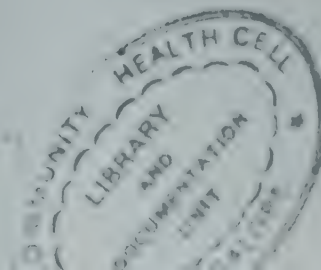
The death of two children was reported from Bilaspur District in Madhya Pradesh. The incident was investigated by Dr. S. Agarwal, Dean, Pt. JNM Medical College, Raipur and Dr. N.G. Prasan, professor of paediatrics, Pt. JNM Medical College, Raipur.

Seventeen children were given measles vaccine in Bodsara village, Janjgir PHC in Bilaspur district on 2.6.88. Seven children were vaccinated with a vial which had been reconstituted the previous day and kept in an earthen pot. All seven children had fever and severe vomiting and diarrhoea. The symptoms started within one hour of vaccination. One child died in the village and the other within 10 minutes of the arrival of the doctor from Janjgir hospital. The other children were provided medical care. These children later developed urticaria and abscess at the site of injection.

Three children vaccinated from the same vial on the previous day did not complain of any reactions.

Ten other children were also vaccinated on 2.6.88 with measles vaccine. The vial was constituted on 2.6.88. Five of these children developed abscesses and two were hospitalized.

The date of the issue of the vaccine vials from the PHC is not mentioned in the report but it was apparently on or before 27.5.88. The vaccine vials were kept in the earthen pot containing sand and water prior to use. Only one syringe was used for the vaccination of all 17 children. The vaccine was given in the gluteal region intramuscularly although it is recommended to be given subcutaneously.



The clinical picture of the children who were administered measles vaccine reconstituted on the day prior to immunization is consistent with the toxic shock syndrome. Post mortem of one child did not reveal any pathological findings.

The poor quality of services and total lack of supervision is evident. The deaths of two children and severe reactions in others resulted due to the negligence of the staff and inadequate monitoring by the supervisory officers.

8.13 Solapur District, Maharashtra, July 1988

The death of 3 children was reported from Solapur district following the administration of measles vaccine. One child was seriously ill in the hospital at the time of investigation. The report of the incident was received the next day by the state health authorities. Investigations were conducted on 16.7.88 by the state Immunization Officer and the Regional Deputy Director of Health Services, Dean of the Medical College and a consulting paediatrician. The state investigation committee investigated the incident on 19-20.7.88.

Eleven children were vaccinated in a PHU in Solapur district on 14.7.88 with measles vaccine and OPV. One child received only OPV. Although DPT was recorded as having been administered, this was denied by the parents of the children. The HW(F) later admitted that DPT vaccine was not given to the children and had been falsely entered in the records. Four children developed severe reactions of fever, vomiting and diarrhoea within two hours of vaccine administration. One child died in the village and another on the way to the hospital the same evening. One child died in the hospital the next morning. One child was hospitalized in serious condition.

Investigations have shown serious lapses in implementation. 3 vials of measles vaccine were issued to the HW(F) on 7.7.88. Two vials were reported by her to have been used on the same day. The third was kept in a 'matka' for over a week. Despite strong circumstantial evidence the HW(F) denied reuse of the reconstituted measles vaccine vial, although 11 children were reported to have been vaccinated from a 10 dose vial.

The HW(F) reported that she had arbitrarily reduced the dosage of measles vaccine from 0.5 ml to 0.3 ml and had vaccinated 11 children from a 10 dose vial of measles vaccine. She had used distilled water kept on the shelf in the subcentre. This was not the diluent supplied with measles vaccine.

She reported abscesses in children some time earlier in her area. The dosage of the vaccine was reduced as she presumed that the abscesses were due to the vaccine. DPT vaccine was not administered along with OPV.

The HW(F) had only 2 syringes and a few needles. Obviously unsterile syringes and needles were being used.

A semi-used vial of OPV batch No. S 122 5A4B MFD 12/87, date of expiry 12/89 was received at CRI on 5.9.88. The vial contained 1 ml. of the vaccine. The vial had been lifted by the police authorities on 16.7.88. The conditions of storage and transportation during the period between 16.7.88 and 5.9.88 are not known. The vial was found to be contaminated with sarcina species, aerobic spore bearing organism and fungus resembling penicillium species. Potency and toxicity tests could not be done as the vaccine was unsterile (CRI test report No. PVT/88/661 dated 21.10.88).

The PHU falls within the field practice area of the Medical College. Solapur has not yet been included under UIP. No training programmes have so far been conducted.

The above indicates poor quality of services and lack of monitoring by the supervisory staff. It is a matter of concern that such conditions should prevail in a field practice area of a medical college.

8.14 Nanded District, Maharashtra, August 1988

The death of an 11 month old child was reported from Narsi village Narsi subcentre, PHC Naigon in Nanded District on 4.8.88. The child died within 10 minutes of measles vaccine administration.

The vaccine was administered in the house of the child. 6 other children were given OPV and DPT vaccines on the same day. The vaccines were given at the Gram Panchayat and also by house to house visits.

According to the information given by the parents the child was cyanosed. The HW(F) and HW(M) immediately took the child on a motorcycle to the PHC but the child died on the way. The child was not examined by the health workers or the two medical officers in the PHC. The child had previously been given two doses each of DPT and OPV and 1 dose of BCG without any reactions.

Autoclaved syringes and needles were used and the vaccines were taken from the PHC in a vaccine carrier on the day of the session. The vaccine was reconstituted 15 minutes prior to use.

Used vaccine vial and 3 unused vials were taken by the FDA (Batch No. BO-848). Post mortem was not conducted due to refusal by the parents.

The cold chain at the PHC was well maintained except that other drugs like pentothal sodium were found in the ILR.

The provisional diagnosis was anaphylactic shock.

8.15 Aizawl District, Mizoram, August 1988

The report of the death of one child was received from Bairabi 'N' subcentre, Aizawl district. The death occurred on 24.8.88. The incident was investigated by an officer of the Directorate of Health Services, Mizoram on 2.9.88.

A one year old female child was administered measles vaccine on 24.8.88 by the HW(F) of the Bairabi subcentre. According to the mother of the child, mild fever, profuse diarrhoea with mucus, severe vomiting, dehydration, restlessness and cyanosis was noted. The child had cold feet about one and a half hour after vaccination and very cold body after about two hours. Reddish discolouration of skin on the back and around the neck was noticed after the child was dead.

The child did not receive medical attention. One capsule of Terramycin (250 mg) and two tablets of enteroquinol in divided doses were administered to the child after about 8 hours of vaccination by the family members.

The vial of measles vaccine which was used had been brought to the subcentre on 12.8.88. The vial was opened after 5 days on 17.8.88. 15 children were reported to have been vaccinated. The same vial was reported to have been used again after 7 days on 24.8.88. The vaccine was kept at ambient temperatures in an almirah. Although adequate number of syringes and needles was available, these were reported to be boiled for 10 to 20 minutes before use. The issue of only one vial of measles vaccine has been confirmed. There was no supervisory check to find out how so many children could have been vaccinated from a single 10-dose vial.

Although the used vial still contained nearly 1 ml of the vaccine, this was not sent for testing.

The SDM&HO was trained after the incident. He has been asked to explain the lapse in supervision.

8.16 Nagaur District, Rajasthan, August 1988

The Health Worker (F) administered measles vaccine to 3 children on 18.8.88 between 9 to 10 A.M. in village Jayal, Distt. Nagaur, Rajasthan. Within one hour after vaccination she was called back as all the 3 children had started vomiting and had diarrhoea alongwith symptoms of shock. One of the children was related to the H.W. (F).

The children were rushed to the Referral Hospital, Jayal. The children were examined by a Medical Officer around 1 P.M. At this time they had high fever,

vomiting, diarrhoea, altered sensorium and flushing of the face and were in shock . The children were provided treatment for revival from shock and rehydration.

On the advice of the CM & HO, Nagaur who personally examined the children around 5 P.M., one child was shifted to Nagaur where he expired in the morning of the 19th August. The other two children died at Jayal the same night. Post mortem was not conducted.

List of children vaccinated

<u>Name</u>	<u>Sex</u>	<u>Age (months)</u>
Ram Kishore	M	18
Basanti	F	10
Rekha	F	18

The vaccine was administered by 2 HWs(F) under the supervision of an HA(F). The vaccine was brought in the morning from the Referral Hospital, Jayal and opened prior to the session. Glass syringes and needles were sterilized in the electric sterilizer at Jayal Hospital and carried to the field.

The vaccine was stored at the Referral Hospital, Jayal. Temperature records were not maintained. It was reported that there was electricity failure for three full days prior to the incident. Apparently no alternative arrangements for the storage of vaccines were made.

It was also noted that there was an epidemic of gastroenteritis in Jayal at the time of the incident. However, no deaths due to gastroenteritis had been reported.

The used vial of measles vaccine, SK&F Rixersart Belgium, date of expiry Oct. '88 batch No. M 115C14A was sent to CRI more than a fortnight after the incident. The conditions of storage and transportation of the sample are not known. The vaccine vial showed fungus contamination on physical examination at CRI. The vaccine was not tested. An unopened vial of the same batch was of standard quality for sterility and toxicity (CRI test report no. 10-4-(i)88-STs dated 16.11.88).

The incident was investigated by Dr. V.N.S. Tomar, Professor and Head of PSM., Dr. H.C. Mathur, Prof. of Paediatrics, Dr. Alka Rao, Asstt. Professor of Microbiology, Dr. Pramod Arya, Dy. Director, Medical and Health Services, Rajasthan on 21.8.88.

8.17 Puri District, Orissa, October 1988

Administration of measles vaccine – Measles vaccine was given by the HW(F) of Kuhudi subcentre, Tangi PHC Puri district on 3rd, 4th and 5th October 1988. The male health worker was assisting the HW(F). 96 children were vaccinated over the three days using 10 vials of the vaccine. The wastage shown was only 4 doses. Services were provided at the doorstep by house to house visits. The medical officers at the PHC were not aware of the work being done at the subcentre and there was no field supervision from that level. No attention had been paid to the fact that a large number of vials had been taken by one subcentre on three consecutive days (according to PHC records).

According to the statement of the HW(F) 11 children were vaccinated from a single vial of measles vaccine containing 10 doses of vaccine in the afternoon of 5.10.88. The vaccine was administered intramuscularly in the the gluteal region against the instructions of subcutaneous injection in the arm. The vaccine was reported to have been taken from the PHC on 5.10.88 in the afternoon by the male HW. The vaccinations were given to the children in the afternoon by house to house visits. The HW(F) could not name any person who could *corroborate* her statement that the vial was opened at the start of the immunization session in the afternoon of the 5th. On the previous two days 39 and 46 children, respectively were vaccinated using 4 and 5 vials (of 10 doses) on each day. Although reuse of vaccine vial from the previous day is denied by the HW(F), this cannot be entirely ruled out as the previous records show that she had been keeping vaccine vials at the subcentre and reusing opened vials (of OPV). Vaccination of 11 children out of 10-dose vial is doubtful.

According to the records of the HW(F) there were 48 syringes (2 ml) in stock at the subcentre. However, only a few syringes were being sterilized by boiling on a stove and carried to the field for convenience. Syringes were reused.

Symptoms – Eleven children vaccinated on 5.10.88 developed vomiting, profuse watery diarrhoea and fever within 2 to 4 hours of vaccination. One child died at home in the middle of the night without being taken for treatment. This child had profuse watery diarrhoea, fever and rash on the abdomen. The parents were unaware of the exact time of death. One child was brought to the PHC early next morning and died within 10 minutes of admission.

A team from the PHC then rushed to the village and brought the remaining nine children to the Capital Hospital, Bhubaneswar where they were admitted for observation and treatment. The children were examined by the Prof. of Paediatrics and Prof. of Medicine, Cuttack Medical College. The children had fever, vomiting and diarrhoea. None of the children showed any signs of dehydration. The children were given corticosteroids parenterally and gentamycin on the presumptive diagnosis of allergic reaction to some contaminant in the

vaccine vial. The children were discharged from the hospital within the next two days. Follow up of these children on 11.10.88 showed that 4 had developed abscesses and the others had induration at the site of injection. 85 children vaccinated on the previous two days did not complain of any symptoms.

Probable cause of reactions and deaths – The symptoms of profuse watery diarrhoea, vomiting and fever are typical in incidents of death following the administration of measles vaccine. One of the children who died also had rash on the abdomen. These symptoms are suggestive of toxic shock syndrome due to contamination. The quality of the services was poor and supervision negligible. A large number of children were vaccinated by door to door visits. Under such circumstances break in the cold chain, use of unsterile syringes and needles and contamination of measles vaccine vial was highly probable. The contamination of the vial and use of unsterile syringes and needles is confirmed by the fact that several of the children have since developed abscesses.

Tests – The vial of measles vaccine used on 5.10.88 was seized by the villagers and could not be obtained for testing. An unopened vial of the same batch (S & F Rimevax batch no. M 123D13A date of expiry April 1989) was found to be of standard quality in respect of sterility and toxicity tests (CRI test report no. 10-4(i)88 STS dated 16.11.88). Post-mortem of the two children was not conducted due to refusal by the parents.

Follow-up action – The Director of FW has recommended disciplinary action against the HW(F) and explanations from the LHV, Medical officer-incharge PHC and the officer-in-charge of the programme at PHC Tangi. Use of measles vaccine was temporarily suspended.

Review of the programme at PHC level – Tangi PHC is an upgraded PHC with a population of 1.12 lakhs. The PHC has 21 subcentres, including the headquarter subcentre. The PHC has 4 allopathic doctors, including a paediatrician and a gynaecologist. One doctor is a specialist in homoeopathy. The responsibility of the programme is with the paediatrician. The area of the PHC has been divided among three MOs for field supervision. Three LHV supervise the work of the HWs(F). All sanctioned posts are filled. Only two subcentres do not have HW(F)s. One is on long leave and the other on deputation. The PHC has one vehicle in working condition.

The PHC did not have any plan of action. There was no evidence to suggest the MOs were involved in the programme or supervised the activities.

Weekly immunization sessions are held on Tuesdays at the PHC. No days have been fixed at the subcentres and sessions are held on an *ad-hoc* basis according to the convenience of the health workers. There is no check on the date of the vaccines from the PHC. These are given by the LHV as and when

requested by the health workers. Some of the subcentres have not been issued vaccines for fairly long periods while others have taken as many as 80 doses on a single day.

The Kuhudi subcentre (where the incident of deaths occurred), for example, had taken 80 doses of OPV on 9.6.88. The performance register of the HW(F) showed vaccinations on 13.6.88 and 18.6.88. The total performance reported during the month of June was 72, including second and third doses. The HW(F) has confessed that vaccine vials were kept by her in a private refrigerator at the subcentre and opened vials were reused.

According to the PHC records 1440 doses of measles vaccine were issued from 1.4.88 to 30.9.88. The reported performance during the period was 1273, giving a wastage rate of less than 12%. The monthly quantities issued varied from 10 doses in June to 990 doses in April. The reported performance by the subcentres did not tally with dates of issue of the vaccine. The storage of vaccines at the subcentre level and reuse of opened vials of vaccine cannot be ruled out in the absence of adequate monitoring and field checks by the PHC.

The records have shown use of opened vials of OPV and DPT at the PHC level itself. On the day of the visit on 14.10.88 an opened vial of OPV was found in stock. Despite the availability of autoclaves syringes and needles are sterilized by boiling. Syringes are reused.

Review of the programme at the district level – Puri district has a population of 34 lakh. Puri was among the first 30 districts to be taken up under the Universal Immunization Programme in 1985-86. According to the reports submitted by the district, a coverage of 63% with 2 doses of TT of estimated number of pregnant women and 80% with 3 doses of OPV of the estimated number of infants in the district in 1987-88. The district reported 42 cases of poliomyelitis during the year.

The Additional Chief District Medical Officer (CDMO) has the overall charge of many programmes, including immunization. The Addl. CDMO is a surgeon and does not have any training or field experience in subjects related to public health. Three District Immunization Officers (DIOs) have been changed over the last one year. The post has been vacant for the last four months. One of the three DIOs posted in Puri was a surgeon. Under the circumstances technical support and guidance or field supervision from the district level was negligible. No action had been taken on a circular related to reactions following measles vaccination issued by the Jt. DHS (FW), Orissa on 11.8.88 or on letters on the subject issued by MOHFW.

Review of the programme at state level – The overall charge of the programme is with the Joint Director of Health Services (Public Health). He is responsible for other programmes besides immunization. The Deputy Director of

Health Services (MCH) was earlier the state EPI officer and responsible for the immunization and MCH programmes in the state. This post is now vacant. The charge of the immunization programme has been given to another officer who is already overworked with her direct responsibilities. There is no senior technical officer looking after the programme full time, thus restricting follow up activities and field visits. Despite their senior positions, no technical officer in the state is entitled to air travel. Their participation in national meetings and workshops is also thus restricted.

General comments – The deaths in Kuhudi subcentre is a reflection of the poor quality of services in general and are not the result of an isolated unfortunate incident. High quality services of the immunization programme is not feasible under the prevailing conditions and casual approach to the services. There is no officer with the necessary training and experience looking after the programme on a full time basis at the state and district levels. Frequent change of officers or posting of those without the necessary background and qualifications lead to an ad-hocism in approach. There was no plan of action at any level. Quality monitoring of the services was totally lacking. Even the risk factors were not identified and followed up. Unless immediate measures are taken to tighten up the services, similar incidents cannot be ruled out. Even in the absence of further deaths, the poor quality of services will not lead to an effective control of the vaccine preventable diseases, defeating the primary purpose of the programme. Unfortunately the quantitative achievement of the number vaccinated is seen to be the end.

The most likely reason of the reactions and the death of children was the contamination of the measles vaccine vial due to the use of unsterile syringes and needles.

9. REPORTS OF SEVERE REACTIONS AND DEATHS FOLLOWING VACCINE ADMINISTRATION (OTHER THAN MEASLES)

1986

9.1 In Aizawl one death was reported in May following the vaccination of 28 children. 4 developed complications. Death occurred on the 15th day. One child developed paralysis due to sciatic nerve injury. Serious lapses were identified including break in the cold chain, faulty administration of vaccines and unsatisfactory sterilization procedures. The vaccines were administered by an unqualified person.

9.2 Fifteen children in Nasik district received DPT and OPV on 29 July 1986. Seven children complained of fever and vomiting and abscesses. One child died on 4 August 1986. Investigations confirmed use of unsterile syringes and needles.

1988

9.3 16 children were vaccinated at Periya Eeachankuzhi villae, PHC Manali, New Town, Madras, an outreach site about 30 kms from Madras on 31.10.1988. 12 of these children received DPT and OPV and 4 children only DPT vaccine. Measles vaccine was not used. Two vials of DPT were used. One of these vials had been opened several days earlier and kept in the refrigerator of a neighbour. One syringe and 10 needles were used. The syringes and needle were immersed in hot water prior to reuse.

Twelve children developed fever, vomiting and diarrhoea. Three of these children aged 12, 13 and 14 months died within 10-12 hours of vaccination. Other children were hospitalized at Stanley Medical College Hospital, Madras and have fully recovered. Blood sampels have been taken for tests. Post mortem has been conducted. Results had not been received at the time of writing the report. Four children are reported to have subsequently developed injection abscesses in the gluteal region.

Left over vaccines could not be traced. The used vials were discarded by the HW(F). An unopened vial from the same PHC is being sent to C.R.I. for testing. The DPT vaccine (10-dose vial) was manufactured at Pasteur Institute of India, Coonoor and OPV (20-doses) was of Belgian origin.

The names of the district and the month of occurrence is shown in Table 6.

Table-6
Names of Districts and Months of Incidents

Sl No.	District	State	Month	Year	Vaccine
1.	Surat	Gujarat	August	1985	Other drug
2.	Kheda	Gujarat	January	1986	Measles
3.	Bombay	Maharashtra	April	1986	Other drug
4.	Aizawl	Mizoram	May	1986	DPT
5.	Kurukshetra	Haryana	June	1986	Measles
6.	Varanasi	U.P.	July	1986	Measles
7.	Nasik	Maharashtra	July	1986	DPT
8.	Bhatinda	Punjab	July	1986	Measles
9.	Rampur	U.P.	April	1987	Measles
10.	Trichur	Kerala	May	1987	Measles
11.	Hissar	Haryana	June	1987	Measles
12.	Cuddapah	A.P.	September	1987	Measles
13.	Vijaywada	A.P.	May	1988	Measles
14.	Aizawl	Mizoram	June	1988	Measles
15.	Dholpur	Rajasthan	June	1988	Measles
16.	Bilaspur	M.P.	June	1988	Measles
17.	Solapur	Maharashtra	July	1988	Measles
18.	Aizawl	Mizoram	August	1988	Measles
19.	Nanded	Maharashtra	August	1988	Measles
20.	Nagaur	Rajasthan	August	1988	Measles
21.	Pun	Orissa	October	1988	Measles
22.	Madras	Tamil Nadu	October	1988	DPT, OPV

Table - 7

Symptoms following measles vaccine administration

Sl. No.	District	Vaccine	Total	R	Symptoms					Died PM		
					F	V	D	C	R	A		
1	2	3	4	5	6	7	8	9	10	11	12	13
1.	Kheda	MEA-12 DPT, OPV-2	13	12	12	10	9	2	0	...	1	N
2.	Kurukshetra	MEA-11 BCG-1 DPT, OPV-4	16	11	11	11	11	0	0	...	2	N
3.	Varanasi	MEA-8 DPT-4 OPV-5 DT-1 TT-3(ANC)	10	9	9	9	9	0	0	...	6	N
4.	Bhatinda	MEA-3 DPT, OPV-2	3	3	3	3	3	0	0	...	2	N
5.	Rampur	MEA-3 TT-1 DT-1	5	5	5	5	5	1	0	...	3*	Y
6.	Trichur	MEA-5	5	5	5	5	5	2	0	3	2	N
7.	Hissar	MEA-18?	18?	7	7	7	7	0	3	4	3	Y
8.	Cuddapah	MEA-6 DPT-?	...	6	6	6	6	0	0	0	6	..
9.	Vijaywada	MEA-5 DPT, OPV-11	13	5	5	5	5	0	0	0	1	N
10.	Aizawl	MEA-2	2	2	2	2	2	0	0	1	1	N
11.	Dholpur	MEA-12	12	12	12	5	5	0	0	6	G	4 N
12.	Bilaspur	MEA-17	17	17	7	7	7	0	0	15	G	2 Y
13.	Solapur	MEA-11	12	4	4	4	4	0	0	0	3	N
14.	Aizawl	MEA-1	1	1	1	1	1	0	0	0	1	N
15.	Nagaur	MEA-3	3	3	3	3	3	0	0	0	3	N
16.	Puri	MEA-11	11	11	11	11	11	0	1	4	2	N

1	2	3	4	5	6	7	8	9	10	11	12	13
17.	Nanded	MEA-16 DPT-5, OPV-6	1	1	-		Anaphylactic shock					
18.	Madras	DPT-16 OPV-12	16	12	12	12	12	0	0	0	3	Y

* Measles vaccine not received by all

F - Fever; V - Vomiting; D - Diarrhoea;
C - Convulsions; R - Rash; R - Reaction;
Y - Yes; N - No

